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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,568	07/31/2000	Leonard G. Presta	A-63470-7/DAV/JJD	6154

7590

11/06/2002

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/06/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

6028,568

Applicant(s)

PRESTA et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 3/12/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 21-28 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 21-28 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1644

The amendment of 3/12/02 has been entered. Claims 1 and 21-28 are pending and under examination.

The amendment has overcome the 112 rejection of record.

Claims 1 and 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is unclear. At line 4 --binding-- must be inserted after "receptor", to be consistent with line 3.

Likewise claim 25 is rejected.

Claims 26-28 each recite a combination of SEQ ID NO: 3 and one of SEQ ID NOS: 11, 11 or 31. It is not clear if both members of each recited combination are derived from only one "loop" of the CH2 domain, as required by base claim 1, at line 5.

Applicant has not disclosed what "loop" each of the recited salvage receptor epitopes are derived from. Hence the examiner is unable to determine whether the recited combinations form an epitope from one or from two "loops". Only the former case would be consistent with claim 1.

Applicant may address this rejection by showing an art known 3D model of the CH2 domain and that the recited sequences of the CH2 domain all lie within one "loop" of the 3D model.

Art Unit: 1644

Also claims 26-28 are unclear because it is believed --binding epitope-- should be recited after "receptor". Applicant's disclosure has indicated these are salvage receptor bindings epitope sequences rather than salvage receptor sequences.

Claims 25-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 25-28 contain new matter in the recitation of each sequence by virtue of reciting "through about".

The examiner finds only the sequences per se disclosed in the specification, figures and original claims. The examiner finds nothing therein to indicate that the lengths of these particular sequences is to be varied --e.g. by deletion of C-terminal residues, or by addition of residues to the C-terminal.

Applicant's amendment of claim 1 has overcome the prior art rejections stated over Paston et al. or Batra et al.

The amendment has overcome the previously stated obviousness type double patenting rejection over the claims of Pat. 6,121,022. However, the amendment has necessitated the following newly stated obviousness type double patenting rejection.

Claims 1 and 22-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-12 and 14 of U.S. Patent No.

Art Unit: 1644

6,096,871. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims encompass the subject matter of those issued.

Specifically, the instant claims encompass the insertion of a salvage receptor binding epitope from the CH2 region of an Ig of any class, while the issued claims are limited to a particular epitope (SEQ ID NO:3, which is recited in instant claim 25) from the CH2 region of an IgG. The sequence combinations recited in instant claims 26-28 are recited in issued claims 2-3, 5, 11-12 and 14. The Fab and (Fab')₂ fragments of instant claim 22 are recited in issued claim 6. The anti-CD18 fragments of instant claim 23 are recited in issued claim 8. The human or humanized polypeptide of instant claim 23 is recited in issued claim 9. A terminal disclaimer is required to assure that ^{Pat.} '871 and any issued instantly retain common ownership.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

Art Unit: 1644

will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9307 for after FINAL responses.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

October 22, 2002

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 1644